

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

determination of the efficacy of "Malva sylvestris" on adult functional constipation in Traditional Iranian Medicine.

Protocol summary

Summary

This study evaluates efficacy of "Malva sylvestris" in patients with functional constipation from Iran. Inclusion criteria: Men and women aged 18–65 years with a history of chronic constipation are eligible for the study. Functional constipation was defined according to the criteria of the Rome III as having at least two or more of the following, during 25% of defecation times: 1, straining; 2, lumpy or hard stools; 3, sensation of incomplete evacuation; 4, manual manoeuvres to facilitate defecation; and 5, fewer than three defecations per week. These criteria should have been fulfilled for the 3 previous months with symptom onset at least 6 months prior to diagnosis. Exclusion criteria includes patients with any of the following conditions: Patients with alarming symptoms (fever, recent weight loss, and anaemia), drug-induced constipation, those with coexisting secondary causes of chronic constipation, including endocrine, metabolic, or neurological disorders, patients with a history of gastrointestinal surgery (exception of appendectomy and cholecystectomy), those with a diagnosis of constipation dominant IBS. This study is Double-blind, randomized, placebo-controlled clinical trial. 110 patients are assigned to two treatment groups, malva sylvestris or placebo groups. The malva sylvestris or placebo is given as syrup with the same shape and colour, twice daily after breakfast and after lunch for 4 weeks. The primary outcome measures are, defaecation rate, stool consistency according to the Bristol Stool Form scale, difficulty on defaecation, sensation of incomplete evacuation, or a need for digital manipulation to facilitate evacuation, are evaluated at baseline, 2 and 4 weeks later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031617032N1**

Registration date: **2014-07-12, 1393/04/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-12, 1393/04/21

Registrant information

Name

Mahin Elsagh

Name of organization / entity

Faculty of Traditional Medicines, Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3395 0154

Email address

elsaghm@yahoo.com

Recruitment status

Recruitment complete

Funding source

Faculty of Traditional Medicines, Tehran University of Medical Sciences.

Expected recruitment start date

2013-12-11, 1392/09/20

Expected recruitment end date

2014-12-11, 1393/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

determination of the efficacy of "Malva sylvestris" on

adult functional constipation in Traditional Iranian Medicine.

Public title

Efficacy of "Malva sylvestris" on functional constipation .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Men and women aged 18–65 as having at least two or more of the following, during 25% of defecation times: very hard and/or hard stools; sensation of incomplete evacuation; straining at defecation; a need for digital manipulation to facilitate evacuation. These criteria should have been fulfilled for the 3 previous months with symptom onset at least 6 months prior to diagnosis. Exclusion criteria: Men and women <18 years; Men and women >65 years; patients with mentioned criteria & drug-induced constipation, patients suffering from secondary causes of chronic constipation, including endocrine, metabolic, or neurological disorders; patients with a history of gastrointestinal surgery (exception of appendectomy and cholecystectomy); those with a diagnosis of constipation dominant IBS; Patients with alarming symptoms (fever, recent weight loss, and anaemia) & constipation.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute for Islamic & Complementary Medicine

Street address

No.9, Pirnia alley, Lalehzar St., Jomhury Ave., Tehran, IRAN

City

Tehran

Postal code

Approval date

2013-03-03, 1391/12/13

Ethics committee reference number

1106/پ26/م/ط

Health conditions studied

1

Description of health condition studied

constipation

ICD-10 code

K59.0

ICD-10 code description

constipation

Primary outcomes

1

Description

defecation rate per week on average

Timepoint

before intervening & 2,4 weeks after treatment

Method of measurement

ROME III questionnaire

2

Description

hard stools

Timepoint

before intervening & 2,4 weeks after treatment

Method of measurement

ROME III questionnaire & Bristol stool form scale

3

Description

need for digital manipulation to facilitate evacuation

Timepoint

before intervening & 2,4 weeks after treatment

Method of measurement

ROME III questionnaire

4

Description

sensation of blockage

Timepoint

before intervening & 2,4 weeks after treatment

Method of measurement

ROME III questionnaire

5

Description

straining of defecation

Timepoint

before intervening & 2,4 weeks after treatment
Method of measurement
ROME III questionnaire

Secondary outcomes

1

Description
rarely dyspepsia
Timepoint
every time patient reports.
Method of measurement
patient report.

Intervention groups

1

Description
In malva sylvestris group, syrup is given 10cc twice daily, 2 hours after breakfast and lunch for 4 weeks.
Category
Treatment - Drugs

2

Description
In placebo group, DW50% syrup approves 10 cc twice daily, 2 hours after breakfast and lunch for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Integrative Functional Gastroenterology Research Center
Full name of responsible person
Mahin Elsagh
Street address
Shariati St, Integrative Functional Gastroenterology Research Center
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Traditional Medicines, Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Shams Ardekani
Street address
on the corner of Behesht St, Vahdat Islami St, Faculty

of Traditional Medicines, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faculty of Traditional Medicines, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Faculty of Traditional Medicines, Iran University of Medical Science
Full name of responsible person
Mahin Elsagh
Position
phd student
Other areas of specialty/work
Street address
No.9, Pirnia alley, Lalehzar St., Jomhury Ave., Faculty of Traditional Medicines, Iran University of Medical Science
City
Tehran
Postal code
Phone
+98 21 3395 0154
Fax
+98 21 3311 1619
Email
Elsaghm@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mahin Elsagh
Position
phd student
Other areas of specialty/work
Street address
No.9, Pirnia alley, Lalehzar St., Jomhury Ave, Faculty

of Traditional Medicines,Iran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 3395 0154

Fax

Email

elsaghm@yahoo.com

Web page address

City

Tehran

Postal code

Phone

+98 21 3395 0154

Fax

+98 21 3311 1619

Email

elsaghm@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Traditional Medicines,Iran University of Medical Sciences

Full name of responsible person

Mahin Elsagh

Position

phd student

Other areas of specialty/work

Street address

No.9, Pirnia alley, Lalehzar St., Jomhury Ave, Faculty of Traditional Medicines,Iran University of Medical Sciences

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty